

REMARKS

The rejection of claims 6, 7, 9, and 10 under 35 USC 112, first paragraph, as failing to comply with the enablement requirement is respectfully traversed.

Applicant has attached hereto a sequence listing for DP-7 and JH4. Also enclosed herewith are certificates indicating the deposit of hybridoma cell lines KCTC 10198BP and KCTC 10199BP.

KCTC 10198BP is a hybridoma cell comprising pHuKR127HC vector, and KCTC 10199BP is a hybridoma cell comprising pHuKR127KC vector. Each vector comprises modified DP7-JH4 and KPK12-JK4, respectively. Moreover, in the last lines of Fig. 2b and Fig. 4b in the specification, JH4 of DP7-JH4 and JK4 of DPK12-JK4, are indicated respectively.

The receipt for the deposit for microorganisms KCTC 10198BP and KCTC 10199BP substantiates the hybridoma cell lines for producing the claimed constructs. As indicated above, each vector comprises a modified BP7-JH4 and BP12-JK4. Thus, a skilled artisan from the publically available sequences and from the disclosures of DP7, JH4, DPK12 and NK, would clearly be enabled to make and use the claimed antibodies. Accordingly, applicant believes the rejection of claims 6, 7, 9 and 12 for lack of enablement under 35 USC 112, first paragraph, should be withdrawn.

The rejection of claim 2 under 35 USC 102(b) as being anticipated by Leong

et al (Cytokine, November 2001, Vol. 16, p. 106-119) is respectfully traversed.

Claim 2 has been modified to limit the claim to a process for preparing a humanized antibody consistent of the steps of (a) and (b) and in that order respectively. It should be noted that step (b) of the present invention is not a process for grafting CDR, but that for grafting SDR. Accordingly, the statement of the Examiner on page 5 of the office Action alleging that the present method steps include (a) performing alanine scanning mutagenesis to optimize the affinity of the murine antibody and (b) grafting the murine CFRs onto the human antibody is correct. As stated above, step (b) of present invention is not a process for grafting CDR but that for grafting SDR. Step (a) of the present invention necessarily proceeds step (b) because step (b) is a step for grafting SDR which are amino acids selected from step (a). Therefore, claim 2 of the present application is novel in view of the fact that step (b) must necessarily follow step (a) and that only SDR among CDR is grafted. The purpose for humanized antibodies in the present invention is for minimizing murine derived sequences. Further differences between the present invention and Leong et al are shown in the following table:

	Leong et al	Present invention
Difference of humanized antibody		
Where to graft antibody from murine antibody	Whole CDR-grafting	Only SDR-grafting
HAMA response	No change (because of whole CDR grafting)	Decreasing HAMA response
		(because of SDR grafting only)
Difference of alanine scanning mutagenesis'		
Alanine scanning candidates	Based on 3-dimensional structure	All amino acid among CDR region, respectively
A standard for determining a specific region	region to increase affinity	region to sharply decrease affinity
Purpose to perform an Alanine scanning mutagenesis	For changing an amino acid to another amino acid	For substituting for an amino acid a murine sequence from
	which has a higher affinity	human CDR
	to murine CDR	

Clearly, the steps of the present method do not correspond to the method steps in Leong.

The amendment of claim 2 limits the process solely to grafting SDR. Accordingly, the rejection of claim 2 under 35 USC 102(b) should be withdrawn.

The rejection of claim 3 under 35 USC 103(a) as being obvious over Maeng et al (Virology, 2000 Vol. 270, p. 9-16) in view of Leong et al is respectfully traversed.

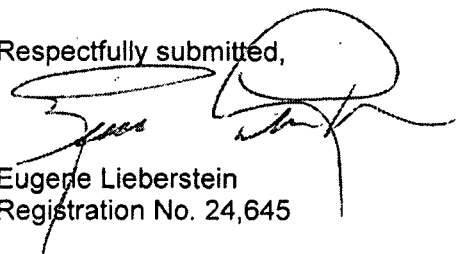
Claim 3 is a dependent claim which depends from claim 2. As explained above, claim 2 has the novel step of grafting only SDR among CDR. This is not taught or suggested in Leong et al or Maeng et al. Accordingly, claim 3 is clearly patentable over the teaching of Leong et al taken alone or in combination with Maeng et al.

Applicant acknowledges that claims 4, 5 and 8 were considered allowable if rewritten in independent form to include all of the limitations of the base claim from which they depend and any intervening claims. Since claims 4, 5 and 8 depend from claim 3, which applicant believes is clearly patentable, claims 4, 5 and 8 are now believed to be in condition for allowance.

Claims 6, 7, 9 and 10 are also dependent claims which depend from claim 3 and are therefore believed patentable for the same reasons as given above.

Reconsideration and allowance of claims 2-10 is respectfully solicited.

Respectfully submitted,



Eugene Lieberstein
Registration No. 24,645

Customer No.: 79681

BAKER & HOSTETLER
45 Rockefeller Plaza
New York, NY 10111
Tel: 212-589-4634
Fax: 212-589-4201

CERTIFICATE OF TRANSMISSION

I hereby certify that this Amendment is being sent to the U.S. Patent Office via EFS-Web to the Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450 on February 17, 2009.

By _____
L. Quagliariello

<<Sequences for DP7 and JH4>>

<210> 1

<211> 80

<212> PRT

<213> Homo sapiens

<220>

<221> DP7

<400> 1

Gln	Val	Gln	Leu	Val	Gln	Ser	Gly	Ala	Glu	Val	Lys	Lys	Pro	Gly	Ala	Ser	Val	Lys	Val
				5						10					15				20
Ser	Cys	Lys	Ala	Ser	Gly	Tyr	Thr	Phe	Thr	Trp	Val	Arg	Gln	Ala	Pro	Gly	Gln	Gly	Leu
				25					30					35					40
Glu	Trp	Met	Gly	Lys	Phe	Gln	Gly	Arg	Val	Thr	Met	Thr	Arg	Asp	Thr	Ser	Thr	Ser	Thr
				45					50					55					60
Val	Tyr	Met	Glu	Leu	Ser	Ser	Leu	Arg	Ser	Glu	Asp	Thr	Ala	Val	Tyr	Tyr	Cys	Ala	Arg
				65					70					75					80

<210> 2

<211> 11

<212> PRT

<213> Homo sapiens

<220>

<221> JH4

<400> 2

Trp	Gly	Gln	Gly	Thr	Leu	Val	Thr	Val	Ser	Ser
				5					10	


BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT
OF MICROORGANISMS FOR THE PURPOSE OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7.1

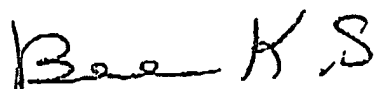
TO : HONG, Hyo Jeong
Clover Apt. 117-201, Dunsan-dong, Seo-ku, Taejeon 302-772,
Republic of Korea

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR: <i>Escherichia coli</i> DH5 α /p α CMV-dhfrC-HuKR127	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: KCTC 10198BP
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
The microorganism identified under I above was accompanied by: <input checked="" type="checkbox"/> a scientific description <input type="checkbox"/> a proposed taxonomic designation (Mark with a cross where applicable)	
III. RECEIPT AND ACCEPTANCE	
This International Depositary Authority accepts the microorganism identified under I above, which was received by it on March 13 2002.	
IV. RECEIPT OF REQUEST FOR CONVERSION	
The microorganism identified under I above was received by this International Depositary Authority on _____ and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on _____.	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Korean Collection for Type Cultures Address: Korea Research Institute of Bioscience and Biotechnology (KRIBB) #52, Oun-dong, Yuseong-ku, Taejeon 305-333, Republic of Korea	Signature(s) of person(s) having the power to represent the International Depositary Authority of authorized official(s):  BAE, Kyung Sook, Director Date: March 16 2002

INTERNATIONAL FORM

issued pursuant to Rule 7.1

TO : HONG, Hyo Jeong
Clover Apt. 117-201, Dunsan-dong, Seo-ku, Taejeon 302-772,
Republic of Korea

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR: CHO/HnKR127 (CHO cell line)	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY: KCTC 10199BF
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
The microorganism identified under I above was accompanied by: <input checked="" type="checkbox"/> a scientific description <input type="checkbox"/> a proposed taxonomic designation (Mark with a cross where applicable)	
III. RECEIPT AND ACCEPTANCE	
This International Depository Authority accepts the microorganism identified under I above, which was received by it on March 13 2002 .	
IV. RECEIPT OF REQUEST FOR CONVERSION	
The microorganism identified under I above was received by this International Depository Authority on _____ and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on _____	
V. INTERNATIONAL DEPOSITORY AUTHORITY	
Name: Korean Collection for Type Cultures Address: Korea Research Institute of Bioscience and Biotechnology (KRIBB) #52, Oun-dong, Yusong-ku, Taejeon 305-333, Republic of Korea	Signature(s) of person(s) having the power to represent the International Depository Authority of authorized official(s):  BAE, Kyung Sook, Director Date: March 16 2002